Supreme Court, U.S.
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No. ——

IN THE

Supreme Court of the United States

OCTOBER TERM, 1990

ERNEST BERGER, Personal Representative
of the Estate of SHEILA BERGER,
Petitioner,

v.

PERSONAL PRODUCTS, INC., *et al.*,
Respondents.

Petition for a Writ of Certiorari to the Washington State Supreme Court

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PETITION FOR A WRIT OF CERTIORARI

BERTHA BARANKO FITZER
Counsel of Record
Attorney-at-Law
949 Market, Suite 545
Tacoma, Washington 98402
(206) 627-4740

WILLIAM J. RUSH
RUSH, HANNULA & HARKINS
715 Tacoma Avenue South
Tacoma, Washington 98402
(206) 383-5388

WILSON - EPES PRINTING CO., INC. - 789-0096 - WASHINGTON, D.C. 20001

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QUESTIONS PRESENTED

Does the Supremacy Clause require a finding that Food and Drug Administration regulations pertaining to the labeling of tampons pre-empt state law compensatory schemes for injuries caused by inadequate warning and inadequate instruction?

Are State compensatory schemes "requirements with respect to a medical device" within the meaning of 21 U.S.C. § 360(k)(a) so as to be pre-empted by federal regulations drafted pursuant to the Medical Device Amendments to the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 360(d) through 360(k)?

LIST OF PARTIES

Plaintiff is Ernest Berger as Personal Representative of the Estate of Shelia Berger.

Defendant is Personal Products, Incorporated, also known as or merged with Johnson & Johnson Baby Products and Johnson & Johnson Products, Incorporated, and Johnson & Johnson, Incorporated.

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PETITION FOR A WRIT OF CERTIORARI

OPINION BELOW

The opinion of the Supreme Court of the State of Washington, dated September 20, 1990, is reported at 115 Wn.2d 267 and is reproduced at pages 1a-10a of the Appendix to this Petition. The Mandate of the Supreme Court of the State of Washington is not reported and appears at Pet. App. 11a-12a. The order of the Washington State Supreme Court denying reconsideration, dated November 19, 1990, is not reported and appears at Pet. App. 13a. The Memorandum Opinion of the Super-

ior Court of the State of Washington, dated March 14, 1989, is not reported and appears at Pet. App. 14a-16a.

JURISDICTION

The judgment of the Supreme Court of the State of Washington was entered on September 20, 1990. Pet. App. 1a-10a. This Court has jurisdiction under 28 U.S.C. § 1257(3).

CONSTITUTIONAL PROVISIONS, STATUTES, AND RULES INVOLVED

This case involves the Supremacy Clause, Article VI, cl. 2, provisions of the Food, Drug and Cosmetic Act, 21 U.S.C. § 360(k); and federal regulations, 21 C.F.R. § 808.1.

The Supremacy Clause provides:

> This Constitution, and the laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

The remaining statutory and regulatory materials are reprinted at Pet. App. 21a-26a.

STATEMENT OF THE CASE

This is a wongful death action by the personal representative of the Estate of Sheila Berger against Personal Products, Inc., the manufacturer of "o.b. tampons." Ms. Berger died on January 5, 1984, of toxic shock syndrome believed to be contracted as a result of using Defendant's tampon product. At the time of her death, Sheila was twenty years old.

Toxic shock syndrome is a rare but serious disease which can be fatal. 21 C.F.R. § 801.430. It is believed to be caused by a toxin-producing strain of bacteria called *Staphylococcus aureus*. Scientists also believe that the use of tampons enhances the growth of the bacteria. *Toxic Shock Syndrome, Recognition and Management of a Diverse Disease*, Postgraduate Medicine, Vol. 73, No. 1, January, 1983. Teenage girls and women under 30 years of age are reported to be more likely to develop tampon-associated toxic shock syndrome than menstruating women of other age groups. *Ibid.* Toxic shock syndrome has occurred in non-menstruating women. *Id.*

Significant evidence links the design of a manufacturer's tampon to the likelihood that the disease will be contracted. *The Relationship of Tampon Characteristics to Menstrual Toxic Shock Syndome*, The Infection Reporter, November, 1987, pp. 73-74. Generally, tampons which have greater absorbency provide increased opportunity for the bacterial growth which creates the toxin. *Ibid.*

Plaintiff brought this action alleging, *inter alia*, that Defendant's tampons were unreasonably dangerous because of inadequate warnings about the risk of contracting toxic shock syndrome. The manufacturer defended based on its compliance with federal regulations and the pre-emption doctrine.

The Medical Device Amendments to the Food and Drug Act, 21 U.S.C. §§ 360(d)-(k) grant the Food and Drug Administration broad authority over medical devices. Section 360(j)(h) of the Act specifically provides for the adoption of regulations for dissemination to the public concerning the safety and effectiveness of a device. Pursuant to this statutory authority, the FDA drafted regulations concerning the labeling of tampon products. It is not disputed that the Defendant complied with the federal regulations governing its product.

Defendant moved for summary judgment on the claim of inadequate warnings. It argued that 21 U.S.C. § 360

(k) pre-empted any state tort action based upon the adequacy of warning in those cases where the product complied with the federal regulations. The Yakima County Superior Court granted this motion for summary judgment. The Court's Memorandum Opinion appears at Pet. App. 14a.

Plaintiff then sought direct review in the Washington State Supreme Court. The Court granted review, but affirmed the decision of the trial court. The opinion of the Washington Supreme Court is reported at 115 Wn.2d 267 and appears at Pet. App. 1a-10a. Plaintiff filed a timely motion for reconsideration. This motion was denied in an unreported ruling. That ruling appears at Pet. App. 13a. The Washington State Supreme Court subsequently mandated the matter to the Yakima County Superior Court. The Court's unreported Mandate appears as Pet. App. 11a.

REASONS FOR GRANTING THE WRIT

I. THIS COURT SHOULD GRANT THE PETITION FOR WRIT OF CERTIORARI TO RESOLVE A SIGNIFICANT ISSUE PERTAINING TO THE SUPREMACY CLAUSE AND A STATE'S RIGHT TO PROVIDE COMPENSATION FOR VICTIMS OF INADEQUATELY LABELED PRODUCTS.

A. The Supremacy Clause, U.S. Const. Art. VI, cl. 2 Invalidates Only Those State Laws Which Interfere With or Are Contrary to Federal Law.

The Supremacy clause, U.S. Const. Art. VI, cl. 2 provides:

> This Constitution, and the laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Con-

stitution or Laws of any State to the Contrary notwithstanding.

In interpreting this section, this Court has long looked to whether state laws "interfere with or are contrary to federal law." *Gibbons v. Ogden*, 9 Wheat. 1, 211, 6 L.Ed. 23(1824). Under the Supremacy Clause, federal law may supersede state law in a variety of ways.

First, in enacting the federal law, Congress may explicitly define the extent to which it intends to pre-empt state law. *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 95-96 (1983). Express pre-emption may be found whenever Congress expressly states its intent to pre-empt or supersede state law. *Hillsborough County, Fla. v. Automated Medical Laboratories*, 471 U.S. 707, 713 (1985). Federal regulations have the same pre-emptive effect as federal statutes. *Fidelity Federal Savings & Loan Assn. v. De La Cuesta*, 458 U.S. 141, 153 (1982).

Second, in the absence of express pre-emptive language, the Court may imply or infer an intent to pre-empt where the statutory or regulatory scheme is sufficiently comprehensive to make reasonable the inference that Congress left no room for supplementary state regulation. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Pre-emption of a whole field may also be inferred where the field is one in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject. *Ibid.*; *Hines v. Davidowitz*, 312 U.S. 52 (1941).

Finally, state law is nullified to the extent that it creates an actual conflict with federal law. *Michigan Canners & Freezers v. Agricultural Bd.*, 467 U.S. 461, 469 (1984). "Such a conflict arises when compliance with both state and federal law is impossible. . . ." *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963). A conflict may also be found when the state law "stands as an obstacle to the accomplishment

and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. at 67 (1941).

B. The Medical Device Amendments to the Food, Drug and Cosmetic Act Do Not Expressly Pre-empt State Product Liability Law.

In 1976 Congress extended the Food, Drug and Cosmetic Act to cover all medical devices intended for human use. 21 U.S.C. §§ 360(d)-(k). Section 360(k)(a) of the Act contains the only statement pertaining to the relationship of the federal legislation to state law. That section provides:

> (a) General rule
>
> Except as provided in subsection (b) of this Section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360(k)(a). Pet. App. 21a. Section (b) of the statute provides a mechanism by which a State may seek an exemption from the terms of the statute. 21 U.S.C. § 360(k)(b). These exemptions are available from the Secretary if the requirement is more stringent than a requirement under the chapter. 21 U.S.C. § 360(b)(1).

Pursuant to the authority of this statute, the Food and Drug Administration promulgated the following regulation:

> 808.1 Scope
>
> (b) Section 521(a) of the act contains special provisions governing the regulation of devices by States

> and localities. That section prescribes a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation or court decision) which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or any other matter included in a requirement applicable to the device under the act.

21 C.F.R. § 808.1(b), Pet. App. 22a.

The legislative history of the 1938 bill clearly manifests the intent of Congress to preserve state tort law remedies. The first draft of the 1938 legislation included a provision for a private federal right of action for damages for violations of the Act:

> Sec. 24. A right of action for damages shall accrue to any person for injury or death proximately caused by a violation of the Act.

Hearings Before a Subcommittee of the Committee of Commerce, U.S. Senate, 73d Cong., 2d Sess., p. 10 (1933). However, this private cause of action was deleted from subsequent drafts on the ground that such a provision would duplicate already existing rights under state law. *See Consumer Federation of America v. Upjohn Co.*, 346 A.2d 725, 731 (D.C. App. 1975); *State of Florida ex rel. Broward County v. Eli Lilly & Co.*, 329 F.Supp. 364, 365 (S.D. Fla. 1971). As the legislative debate reveals, the adamant view was that "The party injured now has every reasonable protection under the law and a right of action for damages . . ." *Hearings Before a Subcommittee of the Committee of Commerce, U.S. Senate*, 73d Cong., 2d Sess., pp. 400, 403, 431 (1933).

The legislative history demonstrates not a debate over whether state tort law would survive under the FDCA

but rather a widely-held assumption that it would and that a federal cause of action would be duplicative. This history explains the Congressional silence in subsequent FDCA amendments concerning the effect of the legislation on state remedies. State tort remedies are so fundamental in our system of federalism that their survival was patently obvious.

In 1976, Congress attempted to address various deficiencies in the FDCA by enacting the Medical Device Amendments which would bring medical devices under the direct suporvision of the FDA.

In introducing the legislation, Senator Edward Kennedy succinctly states its purpose:

> The purpose of this legislation is to protect the health and safety of the American people . . . the legislation is written so that the benefit of the doubt is always given to the consumer. After all it is the consumer who pays with his health and his life for medical device malfunctions.

121 Cong. Rec. 59, 10688 (1975). The Congessional Reports accompanying the Medical Device Amendments contain little discussion of Sec. 360(k). The sole purpose of the pre-emption provision appears to be pre-emption of state drug and device laws which conflicted with the new federal regulatory scheme.

The absence of explicit legislative intent as to the Medical Device Amendments is not fatal to the argument against express pre-emption. The Court looks primarily to the express terms of the statute in determining issues of pre-emption. *Comment, Federal Preemption and the FDA: What Does Congess Want?*, 58 Cinn. L. Rev. 263, 265-266(1989).

Section 360(k) is virtually identical to a provision contained in the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

> [A] State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

7 U.S.C. 136(v)(b). The D.C. Circuit Court of Appeals interpreted the FIFRA pre-emption language as not pre-empting state tort actions or remedies based on the following reasoning:

> The verdict itself does not command Chevron to alter its label—the verdict merely tells Chevron that, if it chooses to continue selling paraquat in Maryland, it may have to compensate for some of the resulting injuries. That may in some sense impose a burden on the sale of paraquat in Maryland, but *it is not equivalent to a direct regulatory command that Chevron change its label. Chevron can comply with both federal and state law by continuing to use the EPA-approved label and by simultaneously paying damages to successful tort plaintiffs such as Mr. Ferebee.* (Emphasis added).

Ferebee v. Chevron Chemical Co., 736 F.2d 1529, 1541 (D.C. Cir.), *cert. denied*, 105 S.Ct. 545 (1984). Similarly, this Court should reject the contention that § 360(k) expressly pre-empts state product liability law.

C. Conflicting Decisions Exist as to Whether Compensatory Tort Systems Are Pre-empted by the Medical Device Amendments to the Food, Drug and Cosmetic Act and Regulations Promulgated Pursuant to Its Authority.

Courts which have been called upon to determine the pre-emptive scope of § 360(k) have reached conflicting results depending on the area of regulation being analyzed. In *Smith v. Pingree*, 651 F.2d 1021 (5th Cir. 1981), the court concluded the Act did not pre-empt a Florida statute governing information to be given purchasers of hearing aids. The New Jersey Supreme Court

reached the same result in *New Jersey Guild of Hearing Aid Dispensers v. Long*, 384 A.2d 795 (1978). There the court opined:

> In specifying a detailed formula for use in determining exactly which state laws are pre-empted by § 521 [§360(k)(a)], Congress has deliberately circumscribed the extent to which its enactment has occupied the field of device regulation. . . . [I]n view of the establishment of this innovative exemption mechanism, it seems accurate to say that there is nothing "implicitly contained in its structure and purpose" from which an unambiguous congressional intent to pre-empt concurrent state regulations is reasonably inferable.

New Jersey Guild of Hearing Aid Dispensers v. Long, 384 A.2d 813-14.

This approach is different from that taken by courts analyzing regulations governing tampons. For instance, a different panel of the Fifth Circuit concluded federal regulations governing tampon labeling pre-empted state product liability law. *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989). No other circuit has specifically addressed the issue.

The Tenth Circuit, however, did affirm a large verdict awarded to a plaintiff in another toxic shock syndrome case. The plaintiff's chief complaint was that the product's warnings were inadequate. The Tenth Circuit rejected Defendant's argument that compliance with the federal standards immunized it from liability. The court noted:

> Playtex argues that the presence of a warning that complied with FDA requirements precludes, as a matter of law, any finding that Playtex exhibited the reckless indifference necessary to support an award of punitive damages. We disagree. As we noted above, compliance with FDA standards is not dispositive of Kansas law if a reasonable manufac-

> turer would have done more. Under these circumstances, compliance with FDA regulations does not preclude punitive damages when there is evidence sufficient to support a finding of reckless indifference to consumer safety.

Olgivie v. International Playtex, Inc., 821 F.2d 1438 (10th Cir. 1987).

Washington appears to be the first state supreme court to reach the issue. In *Berger v. Personal Products*, 115 Wn.2d 267 (1990), the Supreme Court of the State of Washington, followed the *Moore* analysis. It found Congress intended to pre-empt petitioner's state claim for damages based on allegations of improper or inadequate warnings.

The *Berger* opinion and other cases which find pre-emption conflict with this Court's analysis of pre-emption issues. Specifically, Washington failed to recognize that the language of § 360(k) is not sufficient to find an express or implied Congressional intent to pre-empt product liability law. This Court employs a strong presumption against a finding of pre-emption in those areas historically within the province of state and localities. "Where . . . the field that Congress is said to have pre-empted has been traditionally occupied by the States we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. at 230) (citations omitted). Consequently, to prevail on the pre-emption argument in a field relating to the States' historic police powers, the party urging pre-emption must present a showing of pre-emption that is strong enough to overcome the presumption "that state and local regulation of health and safety matters can constitutionally coexist with federal regulation." *Hillsborough County, Fla. v. Automated Medical Laboratories*, 471 U.S. at 714.

Respondents cannot overcome this strong presumption. The Supreme Court of the State of Washington and the Fifth Circuit therefore erred in concluding product liability laws pertaining to inadequate warnings are preempted by federal law.

First, Section 360(k)(b) of the Act allows the existence of more stringent state requirements. Section 360(k) provides an application process for approval of state standards which exceed the federal minimum. That section provides:

> (b) Exempt Requirements
>
> Upon application of a State or political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—
>
> > (1) The requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or
> >
> > (2) the requirement—
> >
> > > (A) is required by compelling local conditions and,
> > >
> > > (B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

21 U.S.C. § 360(k)(b) Subsection (1) of the statute thus specifically allows state regulation when two conditions have been met. The regulation must be approved by the Secretary and the regulation must be stricter than that provided by the Act. Admittedly, Washington's tort laws have not been specifically approved by the Secretary of the Food and Drug Administration.

However, the second requirement has been clearly met. There is little doubt that Respondent's chief complaint concerning Washington's product liability law is that the jury is likely to impose a higher standard of care on the manufacturer of tampons than that contained in the FDA regulations. At minimum, this section of the statute rebuts the assumption that Congress intended to protect manufacturers against stringent state laws which impose higher burdens upon them. Moreover, § 360(b)(1) negates the argument that a more stringent state standard automatically conflicts with federal regulations.

Second, a finding of pre-emption conflicts with Food and Drug Administration interpretations of the Act. "The FDA's statement is dispositive on the question of implicit intent to pre-empt unless either the agency's position is inconsistent with clearly expressed congressional intent or subsequent developments reveal a change in that position." *Hillsborough County, Fla. v. Automated Medical Laboratories*, 471 U.S. at 714, citing *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-45 (1984). In the present case, the FDA has taken the position that Congress did not intend to pre-empt state or local product liability law. In a letter to a Washington attorney, Joseph M. Sheehan, Chief of the FDA regulations staff, opined:

> [I]t is the Food and Drug Administration's (FDA) position that Section 521 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360(k)) pre-empts only state and local requirements that are specifically related to medical devices. Therefore, the FDA believes that Section 521 does not pre-empt general product liability requirements.

Pet. App. 19a, *See also*, Pet. App. 17a-18a; 20a.

Finally, the opinion conflicts with this Court's holding in *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984). In *Silkwood*, this Court reversed an appellate court which had concluded that a state may not impose puni-

tive damages for the escape of radioactive material from a federally licensed nuclear facility. The evidence at trial established that Kerr-McGee had complied with most federal regulations promulgated by the Nuclear Regulatory Commission pursuant to the Atomic Energy Act, 42 U.S.C. § 2011 *et seq.* Despite this compliance, the Court held that state punitive damage awards for nuclear accidents were not pre-empted by federal law.

This Court initially restated prior law which had held that the "Federal Government ha[d] occupied the entire field of nuclear safety concerns, except the limited powers expressly ceded to the States." *Silkwood v. Kerr-McGee Corp.*, 464 U.S. at 622. [Citing, *Pacific Gas & Electric Co. v. State Energy Resources Conservation & Development Comm'n*, 461 U.S. 190 (1983)] The Court then rejected arguments that the fact the federal government had completely occupied a field controlled the issue of pre-emption. It noted:

> We do not suggest that there could never be an instance in which the federal law would pre-empt the recovery of damages based on state law. But insofar as damages for radiation injuries are concerned, preemption should not be judged on the basis that the Federal Government has so completely occupied the field of safety that state remedies are foreclosed but only whether there is an irreconcilable conflict between the federal and state standards or whether the imposition of a state standard in a damages action would frustrate the objectives of federal law. We perceive no such conflict or frustration in the circumstances of this case.

Silkwood v. Kerr-McGee Corp., 464 U.S. at 625-26. Paying both federal fines and state imposed damages for the same incident, observed the Court, would not appear to be physically impossible. *Ibid.*

Justices Blackmun and Marshall dissented from this conclusion. Their dissent, however, merely took issue

with the Court's holding regarding punitive damages. As to compensatory damages, both Justices had no difficulty in concluding that federal law would not pre-empt such an award. The analysis employed in this dissent illustrates why courts err in concluding summarily that compensatory damages are pre-empted in a regulated field.

> It is true that the prospect of compensating victims of nuclear accidents will affect a licensee's safety calculus. Compensatory damages therefore have an indirect impact on daily operations of a nuclear facility. But so did the state statute upheld in *Pacific Gas*. The crucial distinction between compensatory and punitive damages is that the purpose of punitive damages is to regulate safety, whereas the purpose of compensatory damages is to compensate victims. Because the Federal Government does not regulate the compensation of victims, and because it is inconceivable that Congress intended to leave victims with no remedy at all, the pre-emption analysis established by *Pacific Gas* comfortably accommodates—indeed it compels—the conclusion that compensatory damages are not pre-empted whereas punitive damages are.
>
> . . . . Congress intended to rely solely on federal expertise in setting safety standards, and to rely on states and juries to remedy whatever injury takes place under the exclusive federal regulatory scheme. Compensatory damages therefore complement the federal regulatory standards, and are an implicit part of the federal regulatory scheme.

Silkwood v. Kerr-McGee Corp., 464 U.S. at 629-30 (Justice Blackmun, dissenting).

The *Berger* opinion cannot be reconciled with these decisions of this Court. As noted below, this case provides an appropriate forum for correcting misinterpretation of the pre-emption doctrine as it applies to the Medical Device Amendments of the Food, Drug and Cosmetic Act.

D. The Present Case Is an Appropriate Vehicle for Clarifying the Pre-emption Doctrine as It Relates to the Food, Drug and Cosmetic Act, Medical Device Amendments, 21 U.S.C. §§ 360(d)-(k).

The Supreme Court of the State of Washington, like federal district courts before it, reasoned from the existence of comprehensive regulations regarding tampons to the conclusion that state product liability law was pre-empted when it involved an inadequate warning claim. This Court's analysis in *Silkwood* demonstrates that such aborted reasoning may result in an erroneous finding of pre-emption. It does not follow from the fact that an agency or statute regulates a field or sets standards that compensatory awards under state law are therefore precluded. This Court has recognized that the two areas of law can coexist and indeed are necessary to providing a complete legal system. Federal laws may set the standard and impose penalties for noncompliance. But even where a regulated party complies with those regulations, it will not be immune from compensatory tort claims by individuals injured by its conduct. *Silkwood v. Kerr-McGee*, 464 U.S. at 625-26.

This Court has the opportunity of correcting this erroneous interpretation of the pre-emption doctrine in an area constantly being litigated. No fewer than 18 courts have reached the incorrect conclusion that state tort laws are pre-empted by these federal regulations. [See cases cited in *Berger v. Personal Products*, 115 Wn. 2d at 272, n.9.] This in turn has resulted in a large number of plaintiffs being denied their right to compensation. No other case, however, is ripe for this Court's review. If the writ is granted, a timely and important issue can be resolved expeditiously.

CONCLUSION

The petition for writ of certiorari should be granted.

Respectfully submitted,

BERTHA BARANKO FITZER
Counsel of Record
Attorney-at-Law
949 Market, Suite 545
Tacoma, Washington 98402
(206) 627-4740

WILLIAM J. RUSH
RUSH, HANNULA & HARKINS
715 Tacoma Avenue South
Tacoma, Washington 98402
(206) 383-5388

APPENDIX

APPENDIX

IN THE SUPREME COURT
OF THE STATE OF WASHINGTON

No. 56098-6

En Banc

ERNEST BERGER, as Personal Representative,
Appellant,

v.

PERSONAL PRODUCTS, INC., *et al.*,
Respondents.

[Filed Sep. 20, 1990]

Nature of Action: The personal representative of a decedent who had died of toxic shock syndrome brought a products liability action against the manufacturer of the tampons used by the decedent.

Superior Court: The Superior Court for Yakima County, No. 86-2-01249-3, Bruce P. Hanson, J., on April 10, 1989, granted a partial summary judgment dismissing the claims based on inadequate warnings and instructions.

Supreme Court: Holding that state law regarding inadequate warnings and instructions was preempted by federal law, the court *affirms* the judgment.

Rush, Hannula & Harkins, by *William J. Rush* and *Daniel R. Kyler*, for appellant.

Susan J. Robinson, *Gregory C. Sisk*, and *Karr Tuttle Campbell* (*George Gore*, *Victoria L. Vance*, and *Arter & Hadden*, of counsel), for respondents.

IN THE SUPREME COURT
OF THE STATE OF WASHINGTON

Number 56098-6

En Banc

ERNEST BERGER, Personal Representative of the Estate of SHEILA BERGER,

Appellant,

v.

PERSONAL PRODUCTS, INC., a foreign corporation, aka and/or merged with JOHNSON & JOHNSON BABY PRODUCTS, a foreign corporation; and JOHNSON & JOHNSON PRODUCTS, INC., a foreign corporation; and JOHNSON & JOHNSON, INC., a foreign corporation,

Respondents.

Filed Sep. 20, 1990

SMITH, J.—Appellant Ernest Berger, as personal representative of the estate of Sheila Berger, deceased, appeals from a partial summary judgment of the Yakima County Superior Court dismissing his product liability action against respondent Personal Products, Inc. We affirm the trial court.

The sole question we consider is whether under 21 U.S.C. § 360k(a) and 21 C.F.R. § 808.1(b) federal law preempts a state tort action based on the claims of inadequate warnings and instructions about the risk of contracting toxic shock syndrome associated with tampon use when the product complies with federal labeling re-

quirements under 21 C.F.R. § 801.430. Appellant Berger does not dispute respondent's compliance with those regulations. We answer that federal law does preempt a state tort action under these circumstances.

On January 4, 1984, Ms. Sheila Berger, age 20, died of toxic shock syndrome alleged to have been contracted as a result of using respondent's product, "o.b. tampons." [1] In his claims against Respondent Personal Products, Inc., Appellant Berger alleged that Personal Products' tampon was unreasonably dangerous because of its faulty manufacture, faulty design, and inadequate warnings and instructions about the risk of contracting toxic shock syndrome.

Respondent Personal Products, Inc., moved for summary judgment on the claim of inadequate warnings and instructions, arguing that federal statutes and regulations preempt any state tort action based upon the adequacy of warnings when the product complies with federal labeling requirements under 21 C.F.R. § 801.430.

The trial court, the Honorable Bruce P. Hanson, Yakima County Superior Court, granted the motion for partial summary judgment, holding that, under 21 U.S.C. § 360k(a) and 21 C.F.R. § 808.1(b) relating to preemption, federal law preempts a state tort action on this issue. The trial court denied a request by Appellant Berger to enter a final judgment on the warnings and in-

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[1] Toxic shock syndrome is a rare but serious disease which can be fatal. It is believed to be caused by a toxin-producing strain of bacteria called *Staphylococcus aureus*. It is also believed that the use of tampons enhances the growth of the bacteria. Teenaged girls and women under 30 years of age are reported to be more likely to develop tampon-associated toxic shock syndrome than menstruating women of other age groups. Toxic shock syndrome also occurs, however, in nonmenstruating women. The disease is characterized by a marked drop in blood pressure and a physical state of shock. Primary symptoms include a sudden fever (usually 102 degree fahrenheit or more), diarrhea, fainting or near fainting when standing up, dizziness, and a rash resembling a sunburn. 21 C.F.R. § 801.430.

structions issues pursuant to CR 54(b). Appellant Berger then stipulated to dismissal with prejudice of his remaining claims.

Appellant Berger claims that federal statutes and regulations do not preempt a state tort action based on the adequacy of warnings and instructions.

Respondent Personal Products, Inc., asserts that the regulations promulgated by the Food and Drug Administration governing labeling requirements of tampons found in 21 C.F.R. § 801.430 preempt state tort law on this issue under 21 U.S.C. § 360k(a) and 21 C.F.R. § 808.1(b).

The doctrine of federal preemption is derived from the supremacy clause of the United States Constitution, article 6, section 2. Federal law preempts state law when Congress intends to occupy a given field, when state law directly conflicts with federal law, or when state law would hinder accomplishment of the full purposes and objectives of the federal law.[2] Preemption may be either express or implied, and is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose. Federal regulations have the same preemptive effect as federal statutes.[3]

In 1976 Congress enacted extensive and comprehensive amendments to the Food, Drug and Cosmetic Act of 1938, 21 U.S.C. § 301 *et seq.*, which became known as the Medical Device Amendments of 1976, 90 Stat. 539, 21 U.S.C. § 360c-k. Under the amendments, all medical de-

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[2] *Alverado v. WPPSS*, 111 Wn.2d 424, 431, 759 P.2d 427 (1988), *cert. denied*, —— U.S. ——, 104 L. Ed. 2d 153, 109 S. Ct. 1637 (1989).

[3] *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 152-54, 73 L. Ed. 2d 664, 102 S. Ct. 3014, 3022 (1982).

vices intended for human use are required to be classified according to their potential risk in order to insure that each product receives the most appropriate form of regulatory control. The Food and Drug Administration classified tampons as Class II (performance standards) medical devices.[4]

Respondent Personal Products, Inc., asserts that section 360k(a) of the Medical Device Amendments expressly preempts any warnings or instructions claims based on state tort law. That section provides in relevant part:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

Regulations promulgated by the Food and Drug Administration pursuant to this statute reflect this expression of intent to preempt state law.

> [Section 360k(a)] prescribes a general rule that . . . no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or *court decision*), which is different from, or in addition to, any requirement applicable to such device under any provision of the act which relates to the safety or ef-

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[4] 45 Fed. Reg. 12, 715-18 (1980); *see also* 21 C.F.R. § 884.5460; 21 C.F.R. § 884.5470 (1988).

> fectiveness of the device or to any other matter included in a requirement applicable to the device under the act.[5]

(Italics ours.)

In 1982, in response to the discovered association between toxic shock syndrome and tampon use, the Food and Drug Administration adopted labeling requirements for tampons. The regulations required the following consumer information to appear "prominently and legibly, in a package insert or on the package, in terms understandable by the layperson": [6]

> 1. The warning signs of Toxic Shock Syndrome and what to do if the warning signs appear;
>
> 2. The statistical risk of Toxic Shock Syndrome to women using tampons;
>
> 3. The advisability of using tampons with the minimum absorbency needed to control menstrual flow;
>
> 4. The potential for avoiding the risk of getting tampon-associated Toxic Shock Syndrome by not using tampons and the potential for possibly reducing the risk of getting toxic shock syndrome by alternating tampon use with sanitary napkin use during menstrual periods;
>
> 5. The need to seek medical attention before again using tampons if Toxic Shock Syndrome warning signs have occurred in the past, or if women have any questions about Toxic Shock Syndrome or tampon use.[7]

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[5] (Italics ours.) 21 C.F.R. § 808.1(b).

[6] Former 21 C.F.R. § 801.430(d).

[7] *See* 21 C.F.R. § 801.430(d).

In addition to the information to be provided in a package insert, the following "alert statement" must appear "prominently and legibly on the package label":

> ATTENTION: Tampons are associated with Toxic Shock syndrome (TSS). TSS is a rare but serious disease that may cause death. Read and save the enclosed information.[8]

United States District Court addressing this same issue in recent years have almost uniformly held that federal law preempts state tort actions under these circumstances.[9] The United States Court of Appeals for the Fifth Circuit has similarly ruled. In *Moore v. Kimberly-*

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[8] 21 C.F.R. § 801.430(c).

[9] *See Moore v. Kimberly-Clark Corp.*, 676 F. Supp. 731, 734-35 (W.D. La. 1987), *aff'd in part on relevant grounds, rev'd in part*, 867 F.2d 243 (5th Cir. 1989); Krause v. Kimberly-Clark Corp., No. L89-30066CA (W.D. Mich. Jan. 17, 1990); *Lindquist v. Tambrands, Inc.*, 721 F. Supp. 1058, 1063, (D. Minn. 1989); Chapman v. Playtex FP, Inc., No. 89-0718-LC (W.D. La. Nov. 17, 1989); Rockett v. International Playtex, Inc., No. 87-2870 (W.D. La. Oct. 4, 1989); Northrip v. International Playtex, Inc., No. 88-0559-CV-W-1 (W.D. Mo. Sept. 28, 1989); Parrott v. International Playtex, Inc., No. SA CV 88-491 JSL (RWRx) (C.D. Cal. May 15, 1989); Bejarano v. International Playtex, Inc., No. 87-4027 (D. Idaho May 10, 1989); *Cornelison v. Tambrands, Inc.*, 710 F. Supp. 706, 708-09 (D. Minn. 1989); *Rinehart v. International Playtex, Inc.*, 688 F. Supp. 475, 477 (S.D. Ind. 1988); Stucker v. International Playtex, Inc., No. C-87-0440-L(b) (W.D. Ky. Feb. 26, 1988), *rev'd on other grounds*, 865 F.2d 261 (1989); Meyer v. International Playtex, Inc., No. 86-3430 (D.N.J. Dec. 1, 1988); Eason v. Tambrands, Inc., No. 87-11677-A (D.C. Tex. Nov. 29, 1988); *Lavetter v. International Playtex, Inc.*, 706 F. Supp. 722 (D. Ariz. 1988); Briggs v. International Playtex, Inc., No. 86C-540-E (N.D. Okla. Apr. 7, 1988); *Stewart v. International Playtex, Inc.*, 672 F. Supp. 907, 909-10 (D.S.C. 1987); *Edmondson v. International Playtex, Inc.*, 678 F. Supp. 1571, 1574-75 (N.D. Ga. 1987); Ignace v. Playtex Family Prods., Inc., No. 86-C-480C (W.D. Wis. Aug. 14, 1987). But see Muzatko v. International Playtex, Inc., No. 85C-1540 (E.D. Wis. May 14, 1987); Kerns v. International Playtex, Inc., No. C-1-86-297 (S.D. Ohio Apr. 18, 1988).

Clark Corp.,[10] that court affirmed the District Court's grant of summary judgment in favor of the defendant tampon manufacturer with respect to plaintiff's warnings and instructions claims. In doing so, the court concluded that state law claims based on inadequate labeling and warning statements are preempted [11] by 21 U.S.C. § 360k and 21 C.F.R. § 808.1(b).[12]

The court in *Moore* noted that:

> The FDA did not intend to preempt all state laws and regulations pertaining to tampons. This is made clear in [21 C.F.R. § 808.1(d) [13]] which provides that "[s]tate or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act. . . ." The relevant requirements applicable under § 360k are set forth in 21 C.F.R. §§ 801.430, 884.5460, and 884.5470, which declare that tampons are a medical device covered by the Act and outline the liability and warning requirements with respect to TSS [toxic shock syndrome].[14]

The United States District Court for the District of South Carolina in *Stewart v. International Playtex, Inc.*,[15]

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[10] 867 F.2d 243 (5th Cir. 1989).

[11] While affirming the District Court's holding that plaintiff's state tort law warnings and instructions claims were preempted, the United States Court of Appeals for the Fifth Circuit reversed the district court's finding that plaintiff's state tort law design defect claims were preempted.

[12] This regulation was incorrectly cited in *Moore* as 21 C.F.R. § 801.1(d).

[13] This regulation was also incorrectly cited in *Moore* as 21 C.F.R. § 801.1(d).

[14] *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 244-45, (5th Cir. 1989).

[15] 672 F. Supp. 907 (D.S.C. 1987).

granted partial summary judgment for a defendant tampon manufacturer on the ground that the Medical Device Amendments expressly preempted state law. The court in *Stewart* rejected the contention that state tort law should not be considered a state law "requirement" within the meaning of the Medical Device Amendments preemption provision defined in 21 C.F.R. § 808.1(b), stating at pages 909-10:

> On its face, this definition encompasses the actions of a court of law entering judgment against the defendant for compensatory and punitive damages based upon "inadequate warnings". The FDA has therefore determined that a state's common law —to the extent it attempts to regulate matters already addressed by the FDA—shall be considered a § 360k "requirement". South Carolina tort law is, therefore not exempt from § 360k.

At least one reported case does not recognize federal preemption in a product liability action based on inadequate warnings and instructions on the risk associated with tampon use. In *Muzatko v. International Playtex, Inc.*,[16] the United States District Court for the Eastern District of Wisconsin concluded that the Food and Drug Administration's toxic shock syndrome warnings regulations did not rise to the level of a requirement within the meaning of § 360k of the Medical Device Amendments.[17]

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[16] No. 85C-1540 (E.D. Wis. May 14, 1987). In an unpublished ruling, the court in Kerns v. International Playtex, Inc., No. C-1-86-297 (S.D. Ohio Apr. 18, 1988), held that the plaintiffs' inadequate warnings and instructions claims were not preempted by federal statute and regulations.

[17] In a case involving an intrauterine device, *Allen v. G.D. Searle & Co.*, 708 F. Supp. 1142, 1151 (D. Or. 1989), the court noted that there appeared to be a doctrinal split in the federal appellate courts on whether state tort liability constitutes a requirement within the terms of the Medical Device Amendments. However, the court held

The court in that case relied upon *O'Gilvie v. International Playtex, Inc.*,[18] which indicated that the federal regulations were merely minimum standards. The issue of *O'Gilvie*, however, was the propriety of a jury instruction. The question of preemption was not raised and therefore was not an issue.

On the basis of the facts in this case and the authorities cited, we conclude that under 21 U.S.C. § 360k and 21 C.F.R. § 808.1(b), federal law clearly preempts state tort law on tampon labeling and warnings requirements for toxic shock syndrome. The trial court was correct in granting the motion for partial summary judgment in this case based on federal preemption.

/s/ Smith

We affirm the trial court.

WE CONCUR:

/s/ Callow, C.J.

/s/ Dore, A/C/J

/s/ Brachtenbach, J.

/s/ Andersen, J.

/s/ Durham, J.

/s/ Utter, J.

/s/ Dolliver, J.

/s/ Guy, J.

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that the Medical Device Amendments do not apply to the intrauterine device at issue in that case.

[18] 609 F. Supp. 817 (D. Kan. 1985), *aff'd in part, rev'd in part*, 821 F.2d 1438 (10th Cir. 1987).

THE SUPREME COURT OF WASHINGTON

No. 56098-6

Yakima County No. 86-2-01249-3

ERNEST BERGER, Personal Representative of the Estate of SHEILA BERGER,
Appellant,

v.

PERSONAL PRODUCTS, INC., *et al.*,
Respondents.

MANDATE

THE STATE OF WASHINGTON TO: The Superior Court of the State of Washington in and for Yakima County.

This is to certify that the opinion of the Supreme Court of the State of Washington filed on September 20, 1990, became the decision terminating review of this court in the above entitled cause on November 19, 1990. This cause is mandated to the superior court from which the appeal was taken for further proceedings in accordance with the attached true copy of the opinion.

Pursuant to Rule of Appellate Procedure 14.3, costs are taxed as follows: $596.00 awarded to the Respondents Johnson & Johnson, et al. and against Appellants Berger.

Order Denying Motion for Reconsideration was entered herein on November 19, 1990. Copy Attached.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seal of said [SEAL] Court at Olympia, this 21st day of November, 1990.

/s/ C. J. Merritt
C. J. MERRITT
Clerk of the
Supreme Court
State of Washington

cc: William J. Rush
Daniel R. Kyler
Susan J. Robinson
Gregory C. Sisk
Victoria Vance
Yakima Co. Clerk
West Publishing
Reporter

THE SUPREME COURT OF WASHINGTON

No. 56098-6

ERNEST BERGER, as Personal Representative,
Appellant,

v.

PERSONAL PRODUCTS, INC., *et al.*,
Respondents.

ORDER DENYING
MOTION FOR RECONSIDERATION

The Court having decided unanimously that the appellant's motion for reconsideration should be denied,

It is ordered that the motion be and it hereby is denied.

Dated this 19th day of November, 1990.

/s/ Keith M. Callow
Chief Justice

IN THE SUPERIOR COURT
OF THE STATE OF WASHINGTON
IN AND FOR YAKIMA COUNTY

No. 86-2-01249-3

ERNEST BERGER, *et al.*,
Plaintiffs,

vs.

JOHNSON & JOHNSON PRODUCTS, INC., *et al.*,
Defendants.

MEMORANDUM OPINION

This action is brought by the Personal Representative of the Estate of Sheila Berger who died from toxic shock syndrome alleged to have been contracted as a result of using defendant's o.b. tampons.

Among other claims, plaintiff alleges that defendants were negligent in failing to provide adequate warnings and instructions with this product.

Defendants have moved for partial summary judgment based upon the issue of federal pre-emption, it being claimed that the Food and Drug Administration's tampon labeling regulations pre-empts state tort laws. It is not claimed by plaintiffs that defendant's tampon labeling did not comply with such regulations, but rather that such regulations set only minimum requirements and a factual issue remains as to the adequacy of such labeling.

Each party has furnished the Court memoranda and supporting material demonstrating a thorough and even exhaustive search and preparation on this issue.

Defendants' motion is primarily based upon Title 21 U.S.C. Section 360k which provides in part:

> "Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."

and Section 808.1(b) of 21 C.F.R.:

> "[Section 360k(a)] of the [Amendments] contains special provisions governing the regulation of devices by State and localities. That section prescribes a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or *court decision*), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act."

Other statutes and regulations are cited as supportive of their position but need not be repeated or referred to herein.

The Court has read many cases cited and finds the following contained in defendants' various memoranda as very persuasive:

> *Edmondson v. International Playtex, Inc.*, No. C85-306R (U.S.D.C. N.D. Ga.)

Ignace v. International Playtex, Inc., No. 86-C-480-C (U.S.D.C. N.D. WI)

Stewart v. International Playtex, Inc., 672 F. Supp. 907 (D.SC Oct. 8, 1987)

Moore v. Kimberly-Clark Corp., Civil Action No. 86-0560 (U.S.D.C. W.D. La., Dec. 23, 1987)

Lavetter v. International Playtex, Inc., No. 84-788-TUC-RMB (U.S.D.C. D. Az., Jan. 22, 1988)

Stucker v. International Playtex, Inc., No. C-87-0440-L(B) (U.S.D.C. W.D. Ky., Feb. 25, 1988)

To continue this opinion in depth would be only to parrot much of the reasoning in those cases cited as to the issue of federal pre-emption generally and Title 21 U.S.C. Section 301 et. seq. and applicable regulations specifically.

Therefore, defendants' motion for partial summary judgment is granted.

DATED this 14th day of March, 1989.

/s/ Bruce P. Hanson
JUDGE BRUCE P. HANSON

National Women's Health Network
c/o Robert E. Manchester, Esq.
Manchester & O'Neill, P.S.
Attorneys at Law
P.O. Box 1459
Burlington, Vermont 05402-1459

Re: Docket No. 83A-0140/AP

Dear Mr. Manchester:

This letter is in response to your letter of April 25, 1983, submitted on behalf of your client, the National Women's Health Network (the network). You have requested an advisory opinion under 21 CFR 808.5, 10.85, 10.20, and 10.30(c)(1), declaring that section 521 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360k) does not preempt the application of State law injunctive remedies to intrauterine contraceptive devices (IUDs) produced, marketed, and inserted into women prior to the enactment of the Medical Device Amendments of 1976 (Pub. L. 94-295) and still being worn by women in the United States and other countries.

Section 521(a) of the act contains special provisions governing the regulation of devices by States and localities. That section prescribes a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect with respect to a medical device intended for human use any requirement having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act. Under section 521(a) of the act, the act preempts only State or local requirements that directly and specifically relate to devices. For a State provision to be a requirement with respect to a device within the meaning of section 521 of

the act, and thereby a candidate for preemption, it is necessary that the State provision relate to the device itself. There is no indication in the legislative history of section 521(a) that Congress intended that the section preempt State or local requirements respecting general enforcement, including available legal remedies, or State or local statutes that only incidentally apply to devices. Rules or requirements established by States to govern the legal remedies available under the State judicial system are not "requirements with respect to a device" within the meaning of section 521(a) of the act.

FDA also advises that section 521(a) of the act preempts State or local requirements applicable to a device only when FDA has established specific counterpart regulations or there are other specific requirements applicable to a particular device or class of devices under the act; it is necessary that an FDA requirement exist before a State requirement is preempted. There is no FDA counterpart (regulations or specific requirements applicable to IUDs) to the State provisions the network has invoked in *National Women's Health Network, et al. v. A.H. Robins Company, Inc.*, No. 81-0004-N (D. Mass. filed January 2, 1981). Thus, those State provisions are not preempted under section 521(a) of the act.

In conclusion, FDA believes that section 521(a) of the act does not preempt the application to IUDs of State law injunctive remedies. This advisory opinion does not address the merits of the application of such remedies in any action filed by the network in the State of Massachusetts or any other State.

Sincerely yours,

/s/ Joseph P. Hile
JOSEPH P. HILE
Associate Commissioner
for Regulatory Affairs

cc: Jeanne Baker, Esq.
David Fine, Esq.
Silverglate, Gertner,
Baker & Fine
88 Broad Street
Boston, Massachusetts 02110

Cindy Whaley, Esquire
Winston, Cashatt
Attorneys at Law
Seattle First Financial Building
Spokane, Washington 99201

Dear Ms. Whaley:

Enclosed is the information that you requested in our phone conversation of January 27, 1987 regarding preemption and medical devices. As you can see from these FEDERAL REGISTER documents, it is the Food and Drug Administration's (FDA) position that section 521 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360(k)) preempts only state and local requirements that are specifically related to medical devices. Therefore, FDA believes that section 521 does not preempt general product liability requirements.

If I can be of any further assistance to you, please let me know.

Sincerely yours,

/s/ Joseph M. Sheehan
JOSEPH M. SHEEHAN
Chief, Regulations Staff

Enclosures

January 14, 1987

Marlys Marshall, Esq.
8100 East 22nd Street, North
Building 1200
Wichita, Kansas 67226-2312

Dear Ms. Marshall:

As we discussed in our telephone conversation today, I am enclosing a copy of an advisory opinion issued by FDA, stating that state requirements respecting available legal remedies are not "requirements with respect to a device" within the meaning of 21 U.S.C. § 360(k)(a) and consequently, are not preempted by federal law.

If I may be of further assistance, please call me at (301) 443-4350.

Very truly yours,

/s/ Beverly Rothstein
BEVERLY ROTHSTEIN
Associate Chief Counsel
for Enforcement

Enclosures

STATUTES INVOLVED

21 U.S.C. § 360k. State and local requirements respecting devices.

(a) General Rule.

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360(g)(e). Remedies.

The remedies provided for in this section shall be in addition to and not in lieu of any other remedies provided by law.

ART. 808—EXEMPTIONS FROM FEDERAL PREEMPTION OF STATE AND LOCAL MEDICAL DEVICE REQUIREMENTS

Subpart A—General Provisions

§ 808.1 Scope

(a) This part prescribes procedures for the submission, review, and approval of applications for exemption from Federal preemption of State and local requirements applicable to medical devices under section 521 of the act.

(b) Section 521(a) of the act contains special provisions governing the regulation of devices by States and localities. That section prescribes a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act.

(c) Section 521(b) of the act contains a provision whereby the Commissioner of Food and Drugs may, upon application by a State or political subdivision, allow imposition of a requirement which is different from, or in addition to, any requirement applicable under the act to the device (and which is thereby preempted) by promulgating a regulation in accordance with this part exempting the State or local requirement from preemption. The granting of an exemption does not affect the applicability to the device of any requirements under the act. The Commissioner may promulgate an exemption regulation for the preempted requirement if he makes either of the following findings:

(1) That the requirement is more stringent than a requirement under the act applicable to the device; or

(2) That the requirement is required by compelling local conditions and compliance with the requirement would not cause the device to be in violation of any applicable requirement under the act.

(d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

(2) Section 521(a) does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.

(3) Section 521(a) does not preempt State or local permits, licensing, registration, certification, or other requirements relating to the approval or sanction of the practice of medicine, dentistry, optometry, pharmacy, nursing, podiatry, or any other of the healing arts or allied medical sciences or related professions or occupa-

tions that administer, dispense, or sell devices. However, regulations issued under section 520(e) or (g) of the act may impose restrictions on the sale, distribution, or use of a device beyond those prescribed in State or local requirements. If there is a conflict between such restrictions and State or local requirements, the Federal regulations shall prevail.

(4) Section 521(a) does not preempt specifications in contracts entered into by States or localities for procurement of devices.

(5) Section 521(a) does not preempt criteria for payment of State or local obligations under Medicaid and similar Federal, State or local health-care programs.

(6)(i) Section 521(a) does not preempt State or local requirements respecting general enforcement, e.g., requirements that State inspection be permitted of factory records concerning all devices, registration, and licensing requirements for manufacturers and other, and prohibition of manufacture of devices in unlicensed establishments. However, Federal regulations issued under sections 519 and 520(f) of the act may impose requirements for records and reports and good manufacturing practices beyond those prescribed in State or local requirements. If there is a conflict between such regulations and State or local requirements, the Federal regulations shall prevail.

(ii) Generally, section 521(a) does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices. Where, however, such a prohiibtion has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, then the prohibition will be preempted if the requirement is different from, or in addition to, a Federal requirement established under the act. In determining whether such a requirement is preempted, the determinative factor is how the requirement is interpreted

and enforced by the State or local government and not the literal language of the statute, which may be identical to a provision in the act.

(7) Section 521(a) does not preempt State or local provisions respecting delegations of authority and related administrative matters relating to devices.

(8) Section 521(a) does not preempt a State or local requirement whose sole purpose is raising revenue or charging fees for services, registration, or regulatory programs.

(9) Section 521(a) does not preempt State or local requirements of the types that have been developed under the Atomic Energy act of 1954 (42 U.S.C. 2011 note), as amended, the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602 (42 U.S.C. 263b et seq.)) and other Federal statutes, until such time as the Food and Drug Administration issues specific requirements under the Federal Food, Drug, and Cosmetic Act applicable to these types of devices.

(e) It is the responsibility of the Food and Drug Administration, subject to review by Federal courts, to determine whether a State or local requirement is equal to, or substantially identical to, requirements imposed by or under the act, or is different from, or in addition to, such requirements, in accordance with the procedures provided by this part. However, it is the responsibility of States and political subdivisions to determine initially whether to seek exemptions from preemption. Any State or political subdivision whose requirements relating to devices are preempted by section 521(a) may petition the Commissioner of Food and Drugs for exemption from preemption, in accordance with the procedures provided by this part.

(f) The Federal requirement with respect to a device applies whether or not a corresponding State or local requirement is preempted or exempted from preemption.

As a result, if a State or local requirement that the Food and Drug Administration has exempted from preemption is not as broad in its application as the Federal requirement, the Federal requirement applies to all circumstances not covered by the State or local requirement.

[43 FR 18665, May 2, 1978, as amended at 45 FR 67336, Oct. 10, 1980]

§ 808.3 Definitions.

(a) "Act" means the Federal Food, Drug, and Cosmetic Act.

(b) "Compelling local conditions" includes any factors, considerations, or circumstances prevailing in, or characteristic of, the geographic area or population of the State or political subdivision that justify exemption from preemption.

(c) "More stringent" refers to a requirement of greater restrictiveness or one that is expected to afford to those who may be exposed to a risk of injury from a device a higher degree of protection than is afforded by a requirement applicable to the device under the act.

(d) "Political subdivision" or "locality" means any lawfully established local governmental unit within a State which unit has the authority to establish or continue in effect any requirement having the force and effect of law with respect to a device intended for human use.

(e) "State" means a State, American Samoa, the Canal Zone, the Commonwealth of Puerto Rico, the District of Columbia, Guam, Johnston Island, Kingman Reef, Midway Island, the Trust Territory of the Pacific Islands, the Virgin Islands, and Wake Island.

(f) "Substantially identical to" refers to the fact that a State or local requirement does not significantly differ in effect from a Federal requirement.